REMARKS

In an effort to expedite prosecution of this application, Applicant has reviewed the above-identified application and is submitting this Preliminary Amendment that corrects the specification and the claims only. No new matter is included.

Respectfully submitted,

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Date

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In th Specification:

Please amend the specification as follows:

FIELD OF THE INVENTION

This invention relates to an ~~apparatus~~ material and a method of increasing the useful life of an yttria-stabilized zirconia structure when implanted in living tissue.

In th Abstract:

Please amend the abstract as follows:

ABSTRACT

The invention is directed to an ~~apparatus~~ material and a method of substantially eliminating destructive low-temperature, humidity-enhanced phase transformation of yttria-stabilized zirconia in general, as well as eliminating low-temperature degradation of yttria-stabilized tetragonal zirconia polycrystalline ceramic (Y-TZP). The martensitic-type phase transformation from tetragonal to monoclinic is accompanied by severe strength degradation in a moist environment at low-temperature, specifically at room temperature as well as at body temperature. This class of materials has been chosen as the packaging material for small implantable neural-muscular sensors and stimulators because of the high fracture toughness and high mechanical strength. This destructive phase transformation has been substantially eliminated, thus ensuring the safety of long-term implants, by subjecting the sintered components to post-machining hot isostatic pressing, such that the average grain size is less than about 0.5 microns.

In th Claims:

Please amend the claims as follows:

1. (Currently Amended) A method of producing a long-lived, stabilized tetragonal zirconia polycrystal ceramic, comprising the step of hot isostatic pressing said ceramic at a controlled temperature, at a controlled pressure, and in a controlled atmosphere to achieve an average grain size of less than about 0.5 micron, to substantially eliminate open porosity and to increase bulk density to about 100% of theoretical, thereby substantially eliminating low-temperature degradation of said ~~implantable case~~ polycrystal ceramic.

2. (Original) The method according to claim 1 further comprising the step of stabilizing said stabilized tetragonal zirconia polycrystal ceramic with yttria.

3. (Original) The method according to claim 2, wherein said step of stabilizing said ceramic with 3 mole percent of yttria.

4. (Original) The method according to claim 1 further comprising the step of providing said ceramic as an implantable hollow tube.

5. (Original) The method according to claim 4 further comprising the step of providing said hollow tube having a length less than 100 mm, an outside diameter less than 10 mm and a wall thickness less than 2 mm.

6. (Original) The method according to claim 1 comprising the step of hot isostatic pressing at said controlled temperature of 1200°C to 1450°C.

7. (Original) The method according to claim 1 comprising the step of hot isostatic pressing at said controlled pressure of at least 100 MPa.

8. (Original) The method according to claim 1 comprising the step of hot isostatic pressing at said controlled atmosphere in argon.

9. (Original) The method according to claim 1 comprising the step of hot isostatic pressing at said controlled atmosphere in a mixture of 80 volume percent argon and 20 volume percent oxygen.

10. (Original) A method of producing a long-lived, implantable case, said implantable case comprised of a stabilized tetragonal zirconia polycrystal ceramic, wherein the improvement comprises the step of hot isostatic pressing said implantable case at a controlled temperature, at a controlled pressure, and in a controlled atmosphere to achieve an average grain size of less than about 0.5 micron, to substantially eliminate open porosity and to increase bulk density to about 100% of theoretical, thereby substantially eliminating low-temperature degradation of said implantable case.

11. (Original) The method according to claim 10 further comprising the step of stabilizing said stabilized tetragonal zirconia polycrystal ceramic with yttria.

12. (Original) The method according to claim 11, wherein said step of stabilizing said ceramic with 3 mole percent of yttria.

13. (Original) The method according to claim 10 further comprising the step of providing said implantable case as a hollow tube.

14. (Original) The method according to claim 13 further comprising the step of providing said hollow tube having a length less than 100 mm, an outside diameter less than 10 mm and a wall thickness less than 2 mm.

15. (Original) The method according to claim 10 comprising the step of hot isostatic pressing at said controlled temperature of 1200°C to 1450°C.

16. (Original) The method according to claim 10 comprising the step of hot isostatic pressing at said controlled pressure of at least 100 MPa.

17. (Original) The method according to claim 10 comprising the step of hot isostatic pressing at said controlled atmosphere in argon.

18. (Original) The method according to claim 10 comprising the step of hot isostatic pressing at said controlled atmosphere in a mixture of 80 volume percent argon and 20 volume percent oxygen.

19. (Original) A method of producing a long-lived, living tissue implantable microstimulator substantially encapsulated within a hermetically-sealed housing, said housing comprised of an yttria-stabilized tetragonal zirconia polycrystal ceramic hollow tube, said microstimulator being of a size approximately 10 mm in diameter and 100 mm in length and of longitudinal shape capable of implantation in the immediate vicinity of selected areas of the body by expulsion through a hypodermic needle, a first inert, metallic electrode hermetically sealed to said housing at or near one end thereof and a second inert, metallic electrode hermetically sealed to said housing at or near another end thereof, and a substantial portion of said electrodes being exposed outside said microstimulator so as to provide stimulation pulses, wherein the improvement comprises the step of hot isostatic pressing said yttria-stabilized tetragonal zirconia polycrystal ceramic hollow tube at a controlled temperature, at a controlled pressure, and in a controlled atmosphere to achieve an average grain size of less than about 0.5 micron, to substantially eliminate open porosity and to increase bulk density to about 100% of theoretical, thereby eliminating low-temperature degradation of said ceramic hollow tube.

20. (Original) The method according to claim 19 comprising the step of hot isostatic pressing at said controlled pressure of 100 MPa.

21. (Original) The method according to claim 19 comprising the step of hot isostatic pressing at said controlled temperature of greater than 1000°C.

22. (Original) The method according to claim 19 comprising the step of hot isostatic pressing in said controlled atmosphere of argon.

23. (Original) A method of producing a long-lived, implantable case, said implantable case comprised of a stabilized tetragonal zirconia polycrystal ceramic, comprising the steps of:

forming said implantable case sized to have a length less than 100 mm, an outside diameter less than 10 mm and a wall thickness less than 2 mm;

sintering said case to an open porosity of less than 2%;

hot isostatically pressing said implantable case at a controlled temperature, at a controlled pressure, and in a controlled atmosphere to achieve an average grain size of less than about 0.5 micron, to substantially eliminate open porosity and to increase bulk density to about 100% of theoretical, thereby substantially eliminating low-temperature degradation of said implantable case;

polishing said ceramic tube to a surface finish of less than 32 microinch roughness; and

brazing hermetically sealed metal ends on said implantable case.

24. (Original) The method of claim 23, further comprising the step of loading the implantable case in three-point bending to a stress of at least 800 MPa to assure that said case will not fail at a lesser stress.

25. (Original) The method of claim 23, wherein said step of hot isostatically pressing further comprises hot isostatically pressing at a controlled temperature of 1200°C to 1450°C.

26. (Original) The method of claim 23, wherein said step of hot isostatically pressing further comprises hot isostatically pressing at a controlled pressure greater than 100 MPa.

27. (Original) The method of claim 23, wherein said step of hot isostatically pressing further comprises hot isostatically pressing in a controlled atmosphere of argon.

28. (Original) The method of claim 23, further comprising the step of hot isostatically pressing at said controlled temperature, said controlled pressure, and said controlled atmosphere for at least 30 minutes.

29. (Original) A ceramic which is inert to water comprised of:

said ceramic comprised of stabilized tetragonal zirconia polycrystal ceramic;

wherein said ceramic is comprised of a sintered ceramic;

wherein said ceramic is comprised of a hot isostatic pressed ceramic that has been pressed at a pressure in a gas environment for a controlled time in a controlled temperature; and

wherein said ceramic is comprised of a tetragonal phase zirconia.

30. (Original) The implantable microstimulator of claim 29, wherein said pressure exceeds 100 MPa for said controlled time of at least 30 minutes in said gas environment of argon gas at said temperature of 1200° to 1450°C.

31. (Original) The implantable microstimulator of claim 29, wherein said stabilized tetragonal zirconia polycrystal ceramic is yttria stabilized.

32. (Original) An implantable microstimulator comprised of:

a hermetically sealed case which is inert to body fluids;

said microstimulator being of a size approximately 6 mm in diameter and 60 mm in length and of longitudinal shape capable of implantation in the immediate vicinity of selected areas of the body by expulsion through a hypodermic needle;

said case comprised of stabilized tetragonal zirconia polycrystal ceramic;

said case further comprised of metal end caps that are brazed to said ceramic;

wherein said case is comprised of a sintered ceramic;

wherein said case is comprised of a hot isostatic pressed ceramic that has been pressed at a controlled pressure in a controlled gas at a controlled temperature for a controlled time; and

wherein said case is comprised of a tetragonal phase zirconia, said case having an implant life exceeding 50 years.

33. (Original) The implantable microstimulator of claim 32, wherein said controlled pressure exceeds 100 MPa, said time is at least 30 minutes at said pressure exceeding 100 MPa in said gas comprised of argon gas at said temperature of 1200° to 1450°C.

34. (Original) The implantable microstimulator of claim 32, wherein said stabilized tetragonal zirconia polycrystal ceramic is yttria stabilized.